EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-25

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-09-027	Base: 4/1/2010-3/31/2011 Option Period Number 2: 1	Low-tech Decontaminaton

Contractor: Arcadis-US, Inc.

Specify Section and Paragraph of Contract SOW:

Purpose:
☒ Work Assignment
☐ Work Assignment Amendment
☐ Work Plan Approval
☐ Work Assignment Close-Out
☐ Incremental Funding

Period of Performance: From 04/29/10 To 03/31/11

Comments: See attached SOW

☐ Superfund — Accounting and Appropriations Data — ☐ Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2): 22

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
This Action			
Total			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee:	LOE:
Cumulative Approved:		Cost/Fee:	LOE:
Work Assignment Manager Name: Shawn P. Ryan CN=Shawn Ryan/OU=RTP/O=USEPA/C=US (Signature)		03/29/2010 (Date)	Branch/Mail Code: E-343-06 Phone Number: 919-541-0699 FAX Number: 919-541-0496
Project Officer Name: Diane Pierce Diane L Pierce (Signature)		4/23/10 (Date)	Branch/Mail Code: TSB Phone Number: 919-541-2708 FAX Number:
Other Agency Official Name: Paul Lemieux (Signature)		4/22/10 (Date)	Branch/Mail Code: Phone Number: 919-541-0962 FAX Number:
Contracting Official Name: Renita Tyus Renita Tyus (Signature)		4/29/10 (Date)	Branch/Mail Code: Phone Number: 513-487-2094 FAX Number:

STATEMENT OF WORK

ASSESSMENT OF LIQUID AND PHYSICAL DECONTAMINATION METHODS FOR ENVIRONMENTAL SURFACES CONTAMINATED WITH BACTERIAL SPORES

OMIS DCMD 3.41

U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HOMELAND SECURITY RESEARCH CENTER
DECONTAMINATION AND CONSEQUENCE MANAGEMENT DIVISION

I. TITLE

Assessment of Liquid and Physical Decontamination Methods for Environmental Surfaces Contaminated with Bacterial Spores

II. PERIOD OF PERFORMANCE

The period of performance for the work under this work assignment shall be April 1, 2010 through March 31, 2011.

III. SUMMARY OF OBJECTIVES

This work shall estimate the occurrence and potential reduction of viable bacterial spores (i.e, effectiveness) as a function of the remediation activities applied to various surfaces. The work will be done in two tasks. In Task 1, the effectiveness of two decontamination protocols shall be evaluated on sections of walls, floors, or a ceiling comprised of the selected materials. In Task 2, the removal efficiency of wet/vacuum carpet cleaning systems on carpet contaminated with viable bacterial spores shall be determined. Operational parameters such as processing time, physical impacts on materials or decontamination crew, and fate of the viable spores (e.g., contamination of equipment, wash water, filters) shall be determined in both Tasks. The anticipated deliverable will be a step-wise guidance document for on-scene responders and remediation teams.

IV. RELEVANCE

This project supports the mission of the Decontamination and Consequence Management Division (DCMD) within the U.S. Environmental Protection Agency's (U.S. EPA) National Homeland Security Research Center (NHSRC) by providing relevant information pertinent to the decontamination of contaminated areas resulting from an act of terrorism. The project supports the NHSRC's strategic goals as described in detail in the Homeland Security Research Multi-year Strategic Plan (draft, November 26, 2008). Specifically, the project is relevant to Long-Term Goal 2 (LTG-2) which states, "The Office of Solid Waste and Emergency Response (OSWER) and other clients use homeland security research program products and expertise to improve the capability to respond to terrorist attacks affecting buildings and the outdoor environments." This project addresses a direct need expressed by OSWER's National Decontamination Team (NDT). In addition, the project is relevant to the U.S. EPA's Office of Pesticide Programs (OPP) crisis exemption process and OPP's regulatory function under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The U.S. EPA has initiated the Taskforce on Research to Inform and Optimize (TRIO) chemical, biological, and radiological (CBR) terrorist agent response across multiple offices within the Agency. The TRIO group consists of members from NHSRC, OSWER, OPP, and the Regional U.S. EPA offices (e.g., On-Scene Coordinators). Due to the potential relevance of this project in preparing for the Federal response to a wide area anthrax dissemination, this project will be managed by NHSRC with the support of a multidiscipline TRIO project team.

V. BACKGROUND

Under Homeland Security Presidential Directive (HSPD)-10, the U.S. Department of Homeland Security (DHS) is tasked to coordinate with other appropriate Federal departments and agencies, to develop comprehensive plans which, "provide for seamless, coordinated Federal, state, local, and international responses to a biological attack." As part of these plans, the U.S. EPA, in a

coordinated effort with DHS, is responsible for "developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities" to mitigate the risks of contamination following a biological weapons attack.

NHSRC provides expertise and products that can be widely used to prevent, prepare for, and recover from public health and environmental emergencies arising from terrorist threats and incidents. Within NHSRC, DCMD's decontamination research program's goal is to provide expertise and guidance on the selection and implementation of decontamination methods and provide the scientific basis for a significant reduction in the time and cost of decontamination events. The NHSRC's research supports OSWER and OPP. OSWER, through its Special Teams which includes the NDT, supports the emergency response functions carried out by the Regional Offices. OPP supports the decontamination effort by providing expertise on biological agent inactivation and ensuring that the use of pesticides in such efforts is done in accordance with FIFRA. Close collaboration between the different program offices having homeland security responsibilities is sought in order to rapidly increase the U.S. EPA's capabilities to help the Nation recover from a terrorist event involving the intentional release of chemical, biological, or radiological (CBR) materials. Such collaborations are fostered through efforts such as TRIO.

In 2001, the introduction of a few letters containing anthrax spores into the U.S. Postal Service system resulted in the contamination of several facilities. Although most of the facilities in which these letters were processed or received in 2001 were heavily-contaminated, they were successfully remediated with approaches such as fumigation with chlorine dioxide or VHP®. It is well agreed that additional quick, effective and economical decontamination methods having the capacity to be employed over wide areas (outdoor and indoor) are required to increase preparedness for such a release.

In addition to fumigation used in primarily, heavily-contaminated facilities, other cleaning methods were used in secondarily contaminated (e.g., cross-contaminated letters potentially in contact with the anthrax spores containing letters or tracked from primarily contaminated sites) areas or primarily contaminated facilities showing a minimal presence of anthrax spores. These methods included combinations of disposal of contaminated items, vacuuming, and the use of liquid sporicides such as a pH-adjusted bleach solution. Additionally, a combined set of mechanical and chemical procedures (vacuum, scrub/wash and bleach) was successfully used in the decontamination of a small shed contaminated with natural anthrax spores originating from animal hides during a drum-making process[1]. If proven effective, such a "lower-tech" approach involving washing and cleaning with readily available equipment, washes and sporicides would significantly increase EPA's readiness to respond to a wide area release. Currently, data to quantify the effectiveness of such decontamination techniques are not available.

VI. SCOPE

The purpose of this project is to determine the effectiveness and operational parameters for a set of procedures which include washing, cleaning and sporicidal methods for the decontamination of different environmental surfaces contaminated with bacterial spores. In this study, effectiveness is a combination of physical and chemical methods to reduce and/or inactivate spores of *B. anthracis* or a relevant surrogate from a contaminated surface. A lower-tech approach, for the purpose of this effort, is defined as procedures not requiring specialized

materials or equipment (i.e., products available at a local hardware store). The methods used for the remediation of the wooden shed in Danbury, CT[1] will be used to establish the protocols in this study. The overarching goals of this project were given high priority by OSWER's Office of Emergency Management's (OEM) for 2009.

In Task 1, sections of materials positioned as walls, floors, or ceilings shall be contaminated via aerosol release of bacterial spores in a room-size study chamber. Full procedures shall be used on each wall/floor/ceiling set-up in the chamber. Decontamination effectiveness shall be determined as a function of the procedures and wall/floor/ceiling constructions using statistically-designed pre- and post-decontamination sampling strategies. Operational considerations and the fate of the spores shall also be determined. The coupon materials are primarily porous, outdoor construction materials. Some interior materials shall also be included and the decontamination procedure(s) shall be tailored for indoor use (e.g., consideration of what can practically be employed inside a residence).

In Task 2, the unheated carpet cleaner used in EP-C-09-207 WA 0-35 shall be applied to three different types of carpet contaminated with bacterial spores via aerosol deposition within the room-sized test chamber. A minimum of three replicates of each test shall be performed. In a subset of experiments, at least one set of replicates tests will have the cleaning repeated up to four times on the same carpet sections so as to determine the number of cleanings necessary to remove the contaminant spores as completely as possible. More replicate tests may be necessary if the precision of this number of tests is too limited to meet the data quality objectives. The decontaminant to be used in the cleaner shall be either a pH-adjusted bleach solution with a surfactant added (e.g., laundry detergent such as Tide) or a commercially-available hydrogen peroxide/peracetic acid solution (e.g., SporKlenz or Minncare). In addition, the application of the decontaminant directly to the carpet shall be included as comparison to the use of the carpet cleaner.

The results of each task shall be documented in two separate reports. Draft reports shall be provided to the U.S. EPA Work Assignment Manager (EPA WAM) for review and comment. Final reports incorporating comments from the EPA WAM, and including a separate documentation of the disposition of comments, shall also be provided as the final deliverables on this work assignment. All products developed under this SOW (e.g., the above mentioned technical report) must conform to the requirements of EPA's Handbook for Preparing Office of Research and Development Reports (EPA/800/K-95/002). Substantive portions of this handbook can be found at www.epa.gov/nhsrc under the policy and guidance tab.

VII. TECHNICAL APPROACH

The general approach that shall be used to meet the objectives of this project for both Tasks is as follows, as briefly mentioned in the Section VI:

- contamination of materials via aerosol deposition of bacterial spores using the procedure to be provided by the U.S. EPA for this study;
- statistically-designed assessment of contamination (sampling of controls or pre-decontamination [characterization] sampling);
- application of prescribed individual and combined decontamination procedures;

- statistically-designed assessment of residual contamination (post-decontamination sampling);
- analysis of subsequent decontamination procedure residues (e.g., waste water or vacuum filters);
- determination of decontamination effectiveness as measured by log reduction from the surfaces; and
- documentation of operational considerations (e.g., cross-contamination, procedural time, impacts on materials and personnel).

Decontamination can be defined as the process of inactivating or reducing a contaminant in or on humans, animals, plants, food, water, soil, air, areas, or items through physical, chemical, or other methods to meet a cleanup goal. In terms of the surface of a material, decontamination can be accomplished by physical removal of the contamination or via inactivation of the contaminant with antimicrobial chemicals. Physical removal could be accomplished via *in situ* removal of the contamination from the material or physical removal of the material itself (i.e., disposal). Similarly, inactivation of the contaminant can be done *in situ* or after removal of the material for ultimate disposal. During the decontamination activities following the results of the 2001 anthrax incidents, a combination of removal and *in situ* decontamination was used. The balance between the two was facility dependent and factored in many issues (e.g., physical state of the facility); one factor was that such remediation was unprecedented for the United States Government (USG) and no technologies had been proven for such use at the time. The cost of disposal proved to be very significant and was complicated by the nature of the waste (e.g., finding an ultimate disposal site). Since 2001, a primary focus for facility remediation has been on improving the confidence in *in situ* decontamination methods and evaluating waste treatment options to be able to provide information necessary to optimize the decontamination/disposal paradigm; this optimization has a very significant impact on reducing the cost of and time for the remediation effort.

The technical approach to be used throughout this study shall be developed considering the background information provided in Section V and this section. This study shall be done in two major tasks. In Task 1, two full decontamination procedures shall be investigated. The full procedures are:

Procedure 1
(1) Vacuum surfaces with a wet/dry vacuum containing a HEPA-rated filter;
(2) Spray the surface with the pH-adjusted bleach until it remains wetted;
(3) Scrub the surface using a brush (or handle-mounted sponge for painted wallboard) wetted with a detergent solution (pH-adjusted bleach/TSP solution);
(4) Completely cover the surface with the pH-adjusted bleach for the 30-min contact time (reapply every 2 min);
(5) Rinse the entire surface with water using a garden hose (or sponge for painted wallboard);
(6) Vacuum residual standing water from horizontal surfaces with the wet/dry vacuum containing a HEPA-rated filter.

Procedure 2
(1) Vacuum surfaces with a wet/dry vacuum containing a HEPA-rated filter;

(2) Completely cover the surface with pH-adjusted bleach/TSP solution for the desired 30-min contact time (reapply every 2 min);
(3) Rinse the entire surface with water using a garden hose (or sponge for painted wallboard);
(4) Vacuum residual standing water from horizontal surfaces with the wet/dry vacuum containing a HEPA-rated filter.

Walls, floors, or a ceiling of the same materials used in EP-C-09-027 WA 0-25 shall be assembled in the room-size test chamber. All testing shall be performed in accordance with the approved Quality Assurance Project Plan (QAPP), "Assessment of Liquid and Physical Decontamination Methods for Environmental Surfaces Contaminated with Bacterial Spores: Part 2 – Operational-scale Study of Full Decontamination Procedures (October 2009)." Prefabricated walls (Set-up 1) or floors (Set-ups 2 - 4) or a ceiling (Set-up 4) shall be moved into the test chamber for the decontamination study according to the approved test matrix. After the decontamination test corresponding to the test matrix for the first decontamination procedure has been completed, the set-up shall be removed and decontamination of the test-chamber shall be completed before the second test in the matrix shall be initiated. For each set-up, the approved contamination procedure shall be used followed by the statistically-designed characterization sampling. One of two decontamination procedures shall then be used. The materials in the set-up shall be allowed to become visibly dry before post-decontamination sampling shall be performed. In addition to the samples taken from the walls, floors or ceiling, any runoff from the decontamination procedures shall also be collected for analysis. Filters from vacuums, if part of the procedure, shall also be collected for analysis. Air filters shall also be taken inside the test chamber to determine potential reaerosolization of spores due to the cleaning procedure. All samples shall be analyzed for the quantitative determination of viable target spores.

In Task 2, the carpets utilized in EP-C-09-027 WA 0-35 shall be used herein. The carpet shall be affixed to padding and a plywood sub-floor. The floor sections for each test shall be 4 foot by 4 foot. Two floor sections shall be tested concurrently. Contamination shall be done via aerosol deposition in the room-sized test chamber. Vacuum sampling shall be done to confirm contamination, with a target of 1E6 colony forming units (CFUs) per square foot. After characterization sampling, the carpet cleaning procedures (one spraying of decontaminant; one use of carpet cleaner containing the decontaminant) shall be applied to the carpets. After an appropriate drying time, the carpets shall be vacuum sampled. Documentation on the impact of the decontamination procedures on the carpets shall also be performed. For one of the three sets of replicate tests, the cleaning shall be repeated up to four times on the same carpet sections so as to determine the number of cleanings necessary to remove the contaminant spores as completely as possible. All testing shall be performed in accordance with the approved Quality Assurance Project Plan (QAPP), "Determination of the Efficacy of Spore Removal from Carpets using Commercially-available Wet/Vacuum Carpet Cleaning Systems (August 2009)."

All sample analysis is outside of the scope of this work assignment. Samples shall be transferred to the National Risk Management Research Laboratory's (NRMRL) Air Pollution Prevention and Control Division's (APPCD) Microbiology Lab for analysis under a separate work assignment. The coupon, wall, floor, and ceiling fabrication are also outside the scope of this work assignment. The materials shall be prepared by the NRMRL/APPCD Machine Shop under a separate work assignment.

VIII. AFFORDABILITY

Components of this study are expected to be somewhat labor intensive; the decontamination processes, sampling, and laboratory assays will require extensive human resources. Relative to the labor costs, only a minimal amount of expendable materials are required to be purchased by the contractor for use in this effort.

IX. TECHNICAL RISK

The technical risk involved in this project is thought to be minimal. The purpose of the effort is to provide information pertinent to the development of operational strategies for the decontamination methods included in the study. Hence, all information obtained in this project (whether intended or not) is expected to be significantly relevant to this purpose.

X. FACILITIES AND MATERIALS

All work on this project described in this statement of work (SOW) shall be performed at the U.S. EPA's facilities located at 109 T.W. Alexander Dr., Research Triangle Park, NC. This study shall be conducted in the COnsequence ManageMent ANd Decontamination Evaluation Room (COMMANDER) located in H130, the room-size chamber alluded to previously.

XI. TASKS

The effort described in this SOW shall be performed in two tasks, as generally described in Section VII. For both tasks, the test matrices shall include:

- Contamination with *Bacillus subtilis* ATCC 19659 (another BSL-1 level microbe or *Geobacillus* species may substituted by the EPA WAM). The choice of the target test organism and preparation will be done based upon comparison data to *Bacillus anthracis* Ames in terms of resistance to inactivation with sodium hypochlorite and that are most suitable for the aerosolization needs of this effort. The spore preparation will be provided by the EPA WAM for this effort.

- Surface sampling using HEPA vacuum for all surfaces except painted dry wall. Wipe sampling shall be used on the painted dry wall. HEPA vacuum sampling shall be used on the painted dry wall in select instances as noted below.

- The runoff of any liquid (rinsate) applied to the materials shall be collected, neutralized, and submitted to the APPCD Microbiology Lab for quantitative viable spore analysis via direct plating.

- Protocols shall be developed to minimize the risk of contamination or cross-contamination during the testing described in this SOW.

- All test activities shall be fully documented during the activity via narratives in laboratory journals, the use of digital photography and video. The documentation should include, but not be limited to, record of time required for each decontamination step or procedure, visual observations during the procedures, any deviations from the test plans, physical impacts on the materials, and impacts on the decontamination or sampling

personnel.

- The recipe for the pH-amended bleach solution shall be provided by the EPA WAM. The contractor shall confirm that the pH and chlorine content are within the specifications documented in the Quality Assurance Project Plan (QAPP) each test day prior to use of the solution.

- Rinse water shall be confirmed to be free of confounding levels of background contamination prior to the initiation of each test.

- All equipment (e.g., brushes, storage bins, etc.) shall be properly sterilized according to the procedures defined in the QAPP prior to the initiation of each test. The procedure is expected to be soaking or washing hard, non-porous materials with a pH-amended bleach solution. Proper decontamination includes selective verification of a representative number of items to be used in a test.

- All samples shall be transferred to the APPCD Microbiology Lab in sterile primary independent packaging within sterile secondary containment containing logical groups of samples. All samples shall be accompanied by a completed chain of custody form.

- All microbiological analysis for samples described in this SOW shall be performed by the APPCD Microbiology Lab. This analysis is outside of the scope of this SOW.

- The documentation of all analytical procedures, all materials, and coupon fabrication information shall be included in the appropriate QAPPs for the work described in this SOW.

These specific details related to each task are described below.

Task 1 – Operational-scale Study of Full Decontamination Procedures:
The purpose of testing under this task is to determine the effectiveness of refined decontamination procedures documented in Section VII. Testing shall be conducted in the COnsequence ManageMent ANd Decontamination Evaluation Room (COMMANDER) located in H130. This stainless steel (Type 316) test chamber has internal dimensions of 10 ft wide × 8 ft deep × 10 ft high. It is equipped with an airlock containing a decontamination shower. Four chamber set-ups shall be defined:

- Set-up 1 shall consist of four 4 ft wide by 5 ft high walls, one wall of each vertical material type.
- Set-up 2 shall consist of two 4 ft by 4 ft floor sections, one of each of two out of the five horizontal material types.
- Set-up 3 shall consist of two 4 ft by 4 ft floor sections, one of each of two out of the three remaining horizontal material types.
- Set-up 4 shall consist of one 4 ft by 4 ft floor sections and one 4 ft by 4 ft ceiling section; the floor shall consist of the remaining horizontal material type not included in Set-up 2 or 3 and the ceiling shall be the horizontal, painted dry wall

All set-ups are listed in Table 1. Alternative set-ups may be proposed by the contractor based upon the use of COMMANDER and the construction of the walls, floors, and ceiling if it is determined that such changes will allow for the objectives to be met at a reduced effort, decrease the technical risk of the project, or enhance the information obtained (e.g., operational parameters or measure of effectiveness) in meeting the objectives.

Table 1: COMMANDER Experimental Set-ups

Set-up	Material	Orientation	Dimensions
1	Concrete	Wall	4 ft wide × 5 ft high
	Brick	Wall	4 ft wide x 5 ft high
	Rough-cut barn wood	Wall	4 ft wide x 5 ft high
	Painted dry wall	Wall	4 ft wide x 5 ft high
2	Concrete	Floor	4 ft x 4 ft
	Asphalt	Floor	4 ft x 4 ft
3	Sealed pressure treated deck wood	Floor	4 ft x 4 ft
	Brick	Floor	4 ft x 4 ft
4	Carpet	Floor	4 ft x 4 ft
	Painted dry wall	Ceiling	4 ft x 4 ft

For each set-up, two sampling events shall be used:

- During characterization sampling, at least four samples shall be taken on each surface in discrete locations determined to be representative of the entire wall, floor, or ceiling.
- For post-decontamination sampling, at least four samples shall be taken in four additional discrete locations determined to be representative of the entire wall, floor, or ceiling.
- The locations for each sampling event on each surface type shall be predefined in the statistical sampling plan documented in the approved QAPP. Sample sizes shall be 1 ft by 1 ft. HEPA vacuum sampling shall be used on all surfaces with the exception of painted dry wall. Wipe sampling shall be used on the excepted surface. Sampling area sizes for both wipes and HEPA vacuums shall be 1 ft by 1 ft.

Each set-up listed in Table 1 shall be tested independently for each decontamination procedure. For each set-up, the contamination procedure as defined in QAPP shall be used to contaminate the surfaces at the target loading of 1E6 - 1E7 viable spores per sample area. Characterization sampling shall be done in accordance with the statistical sampling strategy and methods defined in the approved final QAPP. The results of the characterization sampling shall be reported to the EPA WAM prior to commencement of the application of the decontamination procedure, ass applicable. In consultation with the contractor, the EPA WAM shall decide whether approval shall be given to the contractor to move forward with the decontamination.

- Alternatively, the appropriate corrective action shall be determined which may include a complete repeat of the test. Upon approval of the EPA WAM, the decontamination task shall be run.

- All rinsate from each wall, floor, or ceiling section of the set-up (as appropriate) shall be collected independently for quantitative analysis of viable target spores. One wet/dry vacuum shall be used per wall, floor, or ceiling section (as appropriate). The wet/dry vacuum samples shall be analyzed independently for each section. A single brush (as appropriate) shall be used for each wall, floor, or ceiling section. A new brush shall be used for each section, i.e., no section shall use a common brush. Soap and water (as appropriate) or bleach solutions (as appropriate) shall be maintained independently for each wall, floor, or ceiling section.

- After the decontamination task, all surfaces shall be allowed to become visibly dry. After at least a period of one day, post-decontamination sampling shall be performed in accordance with the statistical sampling strategy and methods defined in the approved final QAPP.

- After completion of each test, the chamber and all contents shall be thoroughly decontaminated with a proven procedure.

- The set-up shall be removed and appropriate set-up for the next test shall be assembled. The process shall be repeated until all tests are completed.

- A proposed test matrix is shown in Table 2, and described in the approved QAPP. Changes to the matrix in Table 2 may be proposed by the contractor based upon the use of COMMANDER and the construction of the walls, floors, and ceiling if it is determined that such changes will allow for the objectives to be met at a reduced effort, decrease the technical risk of the project, or enhance the information obtained (e.g., operational parameters or measure of effectiveness) in meeting the objectives.

- Any changes to the testing shall be documented via an amendment of the approved QAPP. A Category 3/Applied Research QAPP has been approved by the U.S. EPA for this effort under EP-C-09-027, WA 0-25. The contractor shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this work assignment package (see Attachment #1 to the SOW) and the NHSRC QA requirement as defined in Attachment #2 to the SOW. The QAPP, including any amendments, must be approved by the U.S. EPA in writing (e.g., signature on the approval page) prior to the start of any work. Additional information related to QA requirements can be found at: http://www.epa.gov/quality/qs-docs/r5-final.pdf.

Table 2: Task 2 Proposed Test Matrix

Test	Decontamination Procedure	Set-up
1	Procedure 1	1 (walls)
2	Procedure 1	2 (2 floors)
3	Procedure 1	3 (2 floors)
4	Procedure 1	4 (1 floor, 1 ceiling)
5	Procedure 2	1 (walls)
6	Procedure 2	2 (2 floors)
7	Procedure 2	3 (2 floors)

8	Procedure 2	4 (1 floor, 1 ceiling)

The contractor shall design an MS Excel data reporting sheet template prior to the start of any work that conveys all relevant information from a test. This template shall be approved by the EPA for use, prior to conducting any testing described in this SOW. All photographs and videos shall be properly documented, indicating the exact tests in which they were taken. A log (in MS Excel) of all photographs and videos shall be maintained with the electronic files. The log shall include a description of each photograph and video, and include the test number and date. All electronic files shall be stored in a project folder set up on the EPA's DTRL share drive. All information relevant to a test (reporting sheet, digital photographs, videos, log file) shall be transmitted to the EPA WAM within 1 week from the completion of the sample analysis. This data shall have been QA/QC'd by the contractor prior to transmission. Transmission shall occur via e-mail to the EPA WAM informing him/her that the data is ready for viewing.

A draft final report detailing the test results and lessons learned from the testing shall be submitted to the EPA WAM within 30 days following the completion of the testing. This report shall include documentation of the time required to complete each entire test procedure and all procedural steps. The report shall include any digital photos necessary to illustrate the findings. The draft report shall be submitted by the EPA WAM for review from within EPA, including a Quality Assurance review. A final report incorporating requested changes, correction, and clarification resulting from the review process shall be submitted by the contractor within 15 days from receiving the official comments from the EPA WAM. A separate document detailing the response to comments shall also be submitted to the EPA WAM by the contractor with the final version of the report.

Task 2 – Determination of the Efficacy of Spore Removal from Carpets using Commercially Available Wet /Vacuum Carpet Cleaning Systems:

The purpose of testing under this task is to determine the effectiveness of spore removal from carpet using commercially available carpet cleaners. At least three types of carpet, consistent with those used under EPC-09-027 WA 0-35, shall be used in this study. The section size will be at least 4 ft by 4ft, with the appropriate size determined based upon discussions between the contractor and the WAM. This work shall be done in the COnsequence ManageMent ANd Decontamination Evaluation Room (COMMANDER) located in H130, an 8 ft x 10 ft stainless steel chamber. Aerosol-deposition, as done in Task 1, will be used to contaminate the carpet with bacterial spores at the target loading of 1E6 CFU/square foot. The contractor shall investigate the level of loading of the carpet sections to determine the accuracy and precision of the deposition methodology. Appropriate statistical testing must be conducted to demonstrate the data quality objectives.

The same unheated carpet cleaner used in EP-C-09-27 WA 0-35 shall be utilized here. However, the cleaning solution to be used shall either be a pH-adjusted bleach solution containing a surfactant (e.g,. Tide) or a commercially available hydrogen peroxide/peracetic acid solution. The selection shall be made by the EPAWAM in consultation with the contractor.

A minimum of three replicates of each test shall be performed. A test includes two carpet sections in COMMANDER that are contaminated by an aerosol release of spores, sampled using the vacuum sampling protocol defined in the approved QAPP, decontaminated, and then

sampled after being allowed to dry overnight with 1-3 air exchanges per hour at 30-50% RH. In each test, one carpet section shall be treated with the carpet cleaner while the other shall be treated by saturating the carpet with the decontaminant. In a subset of experiments, at least one set of replicates tests will have the cleaning repeated up to four times on the same carpet sections so as to determine the number of cleanings necessary to remove the contaminant spores as completely as possible. More replicate tests may be necessary if the precision of this number of tests is too limited to meet the data quality objectives.

Sample analysis is outside of the scope of this work assignment. Samples shall be transferred to the National Risk Management Research Laboratory's (NRMRL) Air Pollution Prevention and Control Division's (APPCD) Microbiology Lab for analysis under a separate work assignment.

All testing shall be performed in accordance with the approved Quality Assurance Project Plan (QAPP), "Determination of the Efficacy of Spore Removal from Carpets using Commercially-available Wet/Vacuum Carpet Cleaning Systems (August 2009)." Any necessary changes to the testing to accommodate the efforts described in this SOW shall be done as an amendment of this approved QAPP. The contractor shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this work assignment package (see Attachment #1 to the SOW) and the NHSRC QA requirement as defined in Attachment #2 to the SOW. The QAPP, including any amendments, must be approved by the U.S. EPA in writing (e.g., signature on the approval page) prior to the start of any work. Additional information related to QA requirements can be found at: http://www.epa.gov/quality/qs-docs/r5-final.pdf.

A draft final report detailing the test results and lessons learned from the testing shall be submitted to the EPA WAM within 30 days following the completion of the testing. This report shall include documentation of the time required to complete each entire test procedure and all procedural steps. The report shall include any digital photos necessary to illustrate the findings. The draft report shall be submitted by the EPA WAM for review from within EPA, including a Quality Assurance review. A final report incorporating requested changes, correction, and clarification resulting from the review process shall be submitted by the contractor within 15 days from receiving the official comments from the EPA WAM. A separate document detailing the response to comments shall also be submitted to the EPA WAM by the contractor with the final version of the report.

XII. DELIVERABLE SCHEDULE

The deliverables previously described in this SOW with the scheduled due date are shown in Table 3. The timeline shows an anticipated work assignment initiation date of April 1, 2010.

Table 3: Deliverable Schedule

Task	Deliverable	Due Date
1	Electronic files from each test	One week after completion of all data analysis from the test
1	Draft final report	30 days following completion of testing in Task 1 (7/30/2010)

1	Final report	15 days after receiving U.S. EPA comments
2	Electronic files from each test	One week after completion of all data analysis from the test
2	Draft final report	30 days following completion of testing in Task 2 (9/30/2010)
2B	Final report	15 days after receiving U.S. EPA comments

XIII. REPORTING REQUIREMENTS

- The monthly invoice reports for this work assignment shall provide a detailed description of any equipment or expendables that have been purchased by the contractor for use on the projects discussed herein.
- All data related to this project shall be stored on the U.S. EPA servers in the DTRL share folder.
- Data transfer to the EPA WAM shall occur within one week from the completion of data analysis.
- In lieu of final reports for each or any task, journal papers within each task may be submitted at the discretion of the EPA WAM. The papers shall be authored or co-authored by the EPA WAM, at the discretion of the WAM. To serve in lieu of the final report, the journal articles must contain all of the relevant information that would have appeared in the final report.
- All products developed under this SOW (e.g., the above mentioned technical report) must conform to the requirements of EPA's Handbook for Preparing Office of Research and Development Reports (EPA/800/K-95/002). Substantive portions of this handbook can be found at www.epa.gov/nhsrc under the policy and guidance tab.

XIV. REFERENCES

1. After Action Report – Danbury Anthrax Incident, U.S. EPA Region 1, September 19, 2008.

NHSRC QUALITY ASSURANCE REQUIREMENTS FORM
Attachment 1 to the Statement of Work

I GENERAL INFORMATION

Title:	Assessment of Liquid and Physical Decontamination Methods for Environmental Surfaces Contaminated with Bacterial Spores	
Description:	low-tech decont aminaiton method assessment for materials contaminated with bacterial spores	
Project ID:	DCMD 3.41	
Status:	Original	
Number Ammended:		
QA Category:	III	
Action Type:	Extramural	
Peer Review Category:	IV	
Security Classification:	Unclassified	
Project Type:	Applied Research	
QAPP Status 1:	Endorsed	
QAPP Status 2:	Endorsed	
QAPP Status 3:	Not Applicable	
Vehicle Status:	Existing Vehicle	
Vehicle Type:	Vehicle Number:	EP-C-09-027
	Work Assignment Number:	1-25
	Delivery/Task Order Number:	na
	Modification Number:	na
	Other:	na

*If you are processing an **IAG** or **CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

II SCOPE OF WORK

Yes — Does the Statement of Work contain the appropriate QA language?

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action. The contractor shall prepare a QAPP in accordance with the R-2 and R-5 and/or the attachments provided with the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at http://www.epa.gov/quality/qs-docs/r5-final.pdf

Yes — Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods?
(If "No" then skip to Section IV, and sign the form.)

No — Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA?

Yes Has a QAPP already been approved for the activities specified in the SOW?

Provide the title, date or revision number, and date of QA approval:

Assessment of Liquid and Physical Decontamination Methods for Environmental Surfaces Contaminated with Bacterial Spores: Part 2 – Operational-scale Study of Full Decontamination Procedures (October 2009)

Determination of the Efficacy of Spore Removal from Carpets using Commercially-available Wet/Vacuum Carpet Cleaning Systems (August 2009)."

Does the QAPP require *any* revision by the contractor**

No

No Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use by the contractor? (QA approval must be obtained before the contractor can start work.)

** *The term "contractor" applies loosely here, such that as applicable, this term can also mean "awardee", "cooperator" and/or "grantee". Likewise, the term "contract" includes "agreements" and other vehicles.* ?

III QA DOCUMENTATION OPTIONS

All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. *(R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)*

After Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Not Applicable	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with:
Other	Documentation of the application of QA and QC activities to applicable project(s). Developed in accordance with: Explain: NHSRC QMP and Attachmnet #2 to the SOW
na	Programmatic QA Project Plan with supplements for each specific project, developed in accordance with:
Documentation developed pre-award	Existing documentation of the application of QA and QC activities will be used:

IV SIGNATURE BLOCK

The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. *(Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)*

Shawn P. Lyon 3/29/10 Ramona Alexander, 20

Shawn Ryan NHSRC-DCMD Technical Lead Person	03/29/2010 Date	Eletha Roberts NHSRC-IO QA Staff Member	03/29/2010 Date

QAPP REQUIREMENTS FOR APPLIED RESEARCH PROJECTS
(from Appendix B of the NHSRC QMP)

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

1.1 The purpose of study shall be clearly stated.

1.2 The process, site, facility, and/or environmental system to be tested shall be described.

1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

2.1 Key points of contact for each organization involved in the project shall be identified.

2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.

2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.

3.5 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives shall be included.

SECTION 4.0, SAMPLING PROCEDURES

4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.

4.2 Known site_specific factors that may affect sampling/monitoring procedures shall be described.

4.3 Any site preparation needed prior to sampling/monitoring shall be described.

4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.

4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab).

4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.

4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.

4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.

4.11 Describe how samples are uniquely identified.

4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies required for sample preservation shall be described.

4.13 Holding time requirements shall be noted.

4.14 Procedures for packing and shipping samples shall be described.

4.15 Procedures to maintain chain_of_custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.

4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA_approved or similarly validated methods shall be specified.

5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The specific procedures used to assess all identified QA objectives shall be fully described.

6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.

6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.

7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.

7.5 Data storage requirements for each organization shall be provided.

7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The contents of this document can be referenced to a NHSRC or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

Attachment # 2

NHSRC QA
To the Statement of Work
Requirements/Definitions List

EPAs Quality System Website: http://www.epa.gov/quality
EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html
EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) **a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;**
(2) **an organizational chart showing the position of the QA function;**
(3) **delineation of the authority and responsibilities of the QA function;**
(4) **the background and experience of the QA personnel who will be assigned to the project; and**
(5) **the organization's general approach for accomplishing the QA specifications in the SOW.**

NHSRC QA Requirements/Definitions List
Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☒ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP: QAPP requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP QAPP requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

Applied Research Project - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at http://www.epa.gov/quality/QS-docs/g5m-final.pdf.

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		